Complete Summary

GUIDELINE TITLE

Progestogen-only injectable contraception.

BIBLIOGRAPHIC SOURCE(S)

Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit. Progestogen-only injectable contraception. London (UK): Faculty of Sexual and Reproductive Healthcare; 2009 Jun. 17 p. [101 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit. Progestogen-only injectable contraception. London (UK): Faculty of Sexual and Reproductive Healthcare; 2008 Nov. 17 p. [101 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Pregnancy prevention

GUIDELINE CATEGORY

Counseling
Evaluation
Management

Prevention
Risk Assessment
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Patients
Pharmacists
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide evidence-based recommendations and good practice points for clinicians on the use of progestogen-only injectable contraception as an option to prevent pregnancy

TARGET POPULATION

Women considering use of progestogen-only injectable contraception as an option to prevent pregnancy

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation/Risk Assessment

1. Assessment of medical eligibility criteria for use of progestogen-only injectable contraception
2. Medical history and clinical assessment

Counseling/Management/Treatment

1. Counseling women on the risks, benefits, and uncertainties of progestogen-only injectable contraception
    - Mode of action
    - Contraceptive efficacy
    - Duration of use
    - Return of fertility
    - Side effects
    - Discontinuation
    - Health concerns
    - Drug interactions

    - Non-contraceptive benefits
    - Symptoms requiring medical attention
    - Pregnancy
2. Initiation of progestogen-only injectable contraceptives
    - Postpartum (breast or bottle feeding)
    - Following abortion or miscarriage
3. Depot medroxyprogesterone acetate (DMPA) or norethisterone enanthate (NET-EN) administered as a deep intramuscular injection
    - Emergency resuscitation equipment available
4. Repeat injections and follow up
5. Management of common problems

MAJOR OUTCOMES CONSIDERED

- Contraceptive efficacy
- Unintended pregnancy rate
- Side effects of progestogen-only injectable contraception

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Evidence is identified using a systematic literature review and electronic searches are performed for: MEDLINE (CD Ovid version) (1996–2008); EMBASE (1996–2008); PubMed (1996–2008); The Cochrane Library (to 2008) and the US National Guideline Clearing House. The searches are performed using relevant medical subject headings (MeSH) terms and text words. The Cochrane Library is searched for systematic reviews, meta-analyses and controlled trials relevant to progestogen-only injectables. Previously existing guidelines from the FSRH (formerly the Faculty of Family Planning and Reproductive Health Care), the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization (WHO) and the British Association for Sexual Health and HIV (BASHH), and reference lists of identified publications, are also searched.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Level of Evidence

Ia Evidence obtained from meta-analysis of randomised trials

Ib Evidence obtained from at least one randomised controlled trial

IIa Evidence obtained from at least one well-designed controlled study, without randomisation

IIb Evidence obtained from at least one other type of well-designed quasi-experimental study

III Evidence obtained from well-designed non-experimental descriptive studies, correlation studies and case studies

IV Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Selected key publications are appraised using standard methodological checklists similar to those used by the National Institute for Health and Clinical Excellence (NICE). All papers are graded according to the Grades of Recommendations Assessment, Development and Evaluation (GRADE) system. Recommendations are graded as in the table below, using a scheme similar to that adopted by the Royal College of Obstetricians and Gynaecologists (RCOG) and other guideline development organisations. The clinical recommendations within this Guidance are based on evidence whenever possible. Summary evidence tables are available on request from the Clinical Effectiveness Unit (CEU).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Draft One Guidance document is written, providing recommendations and good practice points based on the literature review. The Clinical Effectiveness Unit (CEU) has overall responsibility for writing the Guidance document. The Multidisciplinary Group and other peer reviewers should highlight inconsistencies and errors or where the text is incomprehensible. A Multidisciplinary Group Meeting is held, comprising stakeholders and including service user representation, representation from the Facility of Sexual and Reproductive Healthcare (FSRH) Education Committee and, where possible, representation from the FSRH Clinical Effectiveness Committee (CEC) and FSRH Council. A one-day meeting is held with the Multidisciplinary Group to discuss the Draft One Guidance document.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendations

A: Evidence based on randomised controlled trials

B: Evidence based on other robust experimental or observational studies

C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point: where no evidence exists but where best practice is based on the clinical experience of the multidisciplinary group

COST ANALYSIS

Evidence suggests that amongst long-acting reversible contraception (LARC) methods, intrauterine devices (IUDs) and intrauterine systems are the most cost-effective methods; however, progestogen-only injectables are more cost-effective than the combined oral contractive (COC) pill even after 1 year of use.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The Draft Two Guidance document is peer reviewed by the Multidisciplinary Group and the Facility of Sexual and Reproductive Healthcare (FSRH) Clinical Effectiveness Council (CEC). All written feedback on the Draft Two Guidance document is tabulated and the Clinical Effectiveness Unit (CEU) response to these comments is outlined. The Draft Three Guidance document is prepared based on written feedback and is sent to the Multidisciplinary Group and the FSRH CEC. In addition, two independent reviewers are identified by the CEC to provide feedback at this stage. Only minor comments can be accepted at this stage. The Final Guidance document is published by the FSRH. Proofreading of the Guidance is then performed by three members of the CEU team independently and comments collated and sent back by the Unit Director. A portable document format (PDF) version of the Guidance is made available on the FSRH website.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the Faculty of Sexual & Reproductive Healthcare (FSRH) and the National Guideline Clearinghouse (NGC): The print version of this Clinical Effectiveness Unit (CEU) Guidance Document (issued in November 2008) contained some inconsistencies that the CEU has corrected in the June 2009 version. These corrections are to Table 1: United Kingdom (UK) Medical Eligibility

Criteria for Contraceptive use for progestogen-only injectable use (page 2 in the original guideline document), Timing of repeat injections (page 6 in the original guideline document), and Table 3: Summary of indications for emergency contraception following late progestogen-only injections (page 7 in the original guideline document). The recommendations below are unchanged.

The recommendation grades (**A to C**, **Good Practice Point**) are defined at the end of the "Major Recommendations" field.

Which women are eligible to use progestogen-only injectable contraception?

Health professionals should be familiar with the United Kingdom Medical Eligibility Criteria (UKMEC) for progestogen-only injectable contraceptive use. (**Good Practice Point**)

Table: Definitions of *UK Medical Eligibility Criteria* for Contraceptive Use Categories

UKMEC Definition of Category	
Category	
UKMEC 1	A condition for which there is *no restriction* for the use of the contraceptive method.
UKMEC 2	A condition for which the *advantages of using the method generally outweigh the theoretical or proven risks*.
UKMEC 3	A condition where the *theoretical or proven risks usually outweigh the advantages* of using the method.[a]
UKMEC 4	A condition which represents an *unacceptable health risk* if the contraceptive method is used.

[a]The provision of a method to a woman with a condition given a UKMEC Category 3 requires expert clinical judgement and/or referral to a specialist contraceptive provider since use of the method is not usually recommended unless other methods are not available or not acceptable.

What should clinicians assess when a woman is considering progestogen-only injectable contraception?

A medical history (including sexual history), together with consideration of the UKMEC recommendations, should be used to assess the appropriateness of progestogen-only injectable contraception. (**Good Practice Point**)

What information should be given to women considering progestogen-only injectable contraception?

Mode of Action

Women should be informed that progestogen-only injectable contraception acts primarily by inhibition of ovulation. (**Grade C**)

Contraceptive Efficacy

Women should be advised that the failure rate with the progestogen-only injectable given within license every 12 weeks is very low (<4 in 1000 over 2 years). (**Grade A**)

Return of Fertility

Women should be advised that there can be a delay of up to 1 year in the return of fertility after discontinuation of progestogen-only injectable contraception. (**Grade C**)

Women who do not wish to conceive should be advised to start another contraceptive method before or at the time of the next scheduled injection even if amenorrhoeic. (**Good Practice Point**)

Side Effects

Bleeding Changes

Women should be informed about the altered bleeding patterns that usually occur with the use of a progestogen-only injectable contraceptive. (**Good Practice Point**)

Up to 70% of depot medroxyprogesterone acetate (DMPA) users are amenorrhoeic at 1 year of use. (**Grade B**)

Weight Change

Women should be advised that there is an association between DMPA use and weight gain. (**Grade C**)

Mood Change, Libido and Headache

Women should be advised that there is no evidence of a causal association between the use of progestogen-only injectable contraceptives and mood change, libido or headache. (**Grade C**)

Discontinuation

Women should be informed that up to 50% of progestogen-only injectable contraceptive users will discontinue by 1 year, and that the most common reason for discontinuation is changes to bleeding pattern. (**Grade B**)

Women should be informed about the main reasons for discontinuation of progestogen-only injectable contraception and be given appropriate oral and written advice. (**Grade A**)

Health Concerns

Bone Mineral Density (BMD)

Women should be informed that progestogen-only injectable contraceptive use is associated with a small loss of BMD, which is usually recovered after discontinuation. (**Grade B**)

Women should be advised that there is no available evidence on the effect of depot medroxyprogesterone acetate (DMPA) on long-term fracture risk. (**Good Practice Point**)

In women aged under 18 years DMPA can be used as first-line contraception after consideration of other methods. (**Grade C**)

Women using DMPA who wish to continue use should be reviewed every 2 years to assess individual situations and discuss the benefits and potential risks, and be supported in their choice of whether or not to continue. Use may continue to age 50 years. (**Good Practice Point**)

Drug Interactions

Women should be informed that the efficacy of progestogen-only injectable contraception is not reduced with concurrent use of medication (including antibiotics and liver enzyme-inducing drugs) and the injection intervals do not need to be reduced. (**Grade C**)

Symptoms Requiring Medical Attention

Women should be advised to return if they experience any signs or symptoms of infection at the site of injection. (**Good Practice Point**)

When can progestogen-only injectable contraceptives be started?

Initiation of Progestogen-Only Injectable Contraceptives in Special Circumstances

Postpartum

Women can start a progestogen-only injectable contraceptive up to Day 21 postpartum to provide immediate contraceptive protection. If started after that time another method of contraception or abstinence is required for 7 days. (**Grade C**)

Progestogen-only injectable contraception can be safely used by women who are breastfeeding. (**Grade B**)

Following Abortion or Miscarriage

Progestogen-only injectable contraception may be given following surgical abortion (or second part of) medical abortion or miscarriage. If administered within 5 days after the abortion or miscarriage then additional contraceptive protection or abstinence is not required. (**Grade C**)

Practical Procedures for Administering a Progestogen-Only Injectable Contraception

Emergency Equipment for Administering Progestogen-Only Injectable Contraceptive

Emergency resuscitation equipment must be available in all settings where progestogen-only injectable contraception is administered and local referral protocols must be in place for women who require further medical input. (**Grade C**)

Ongoing Use and Follow-Up of Progestogen-Injectable Contraception and Follow-Up

Timing of Repeat Injections

Women should be advised to return every 12 weeks for a repeat injection of DMPA (or every 8 weeks for norethisterone enanthate [NET-EN]). (**Grade C**)

If necessary, a repeat progestogen-only injectable contraceptive can be given up to 2 weeks early (i.e., 10 weeks for DMPA and 6 weeks for NET-EN). (**Grade C**)

A repeat injection of progestogen-only injectable contraception can be given up to 2 weeks late (i.e., 14 weeks since the last DMPA and 10 weeks for NET-EN) without additional contraception (unlicensed). (**Grade C**)

The decision to provide a further DMPA injection and advice regarding the need for additional contraception should be considered individually, assessing the risk of pregnancy, the duration of use and the method (e.g., one previous injection or using DMPA for the last 5 years). (**Good Practice Point**)

Managing Common Problems Associated with DMPA Use

Unacceptable Bleeding

Clinicians managing women who experience unacceptable bleeding while using a progestogen-only injectable contraceptive should take a sexual history, establish risk of sexually transmitted infections (STIs) and consider possible gynaecological pathology. (**Grade C**)

Women using progestogen-only injectable contraception who have unacceptable bleeding but wish to continue with this method may consider the use of a combined oral contraceptive (COC) pill (if appropriate) as a short-term treatment. (**Grade C**)

Definitions:

Grades of Recommendations

A: Evidence based on randomised controlled trials (RCTs)

B: Evidence based on other robust experimental or observational studies

C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point: Where no evidence exists but where best practice is based on the clinical experience of the multidisciplinary group

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of a progestogen-only injectable for contraception

POTENTIAL HARMS

Altered bleeding patterns usually occur with use of a progestogen-only injectable contraceptive. 70% of depot medroxyprogesterone acetate (DMPA) users are amenorrhoeic at one year use.

CONTRAINDICATIONS

CONTRAINDICATIONS

A current diagnosis of breast cancer is a condition which represents an unacceptable health risk if progestogen-only injectable contraception is used (United Kingdome Medical Eligibility Criteria [UKMEC] 4)

QUALIFYING STATEMENTS

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This document is not intended to serve alone as a standard of medical care, as this should be determined individually based on available clinical information.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Staff Training/Competency Material

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit. Progestogen-only injectable contraception. London (UK): Faculty of Sexual and Reproductive Healthcare; 2009 Jun. 17 p. [101 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2008 Nov (revised 2009 Jun)

GUIDELINE DEVELOPER(S)

Faculty of Sexual and Reproductive Healthcare - Professional Association

SOURCE(S) OF FUNDING

Faculty of Sexual and Reproductive Healthcare

GUIDELINE COMMITTEE

Clinical Effectiveness Unit

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Clinical Effectiveness Unit (CEU): Dr Gillian Penney (Acting Chairperson for Expert Group); Dr Susan Brechin (Unit Director); Ms Lisa Allerton (Research Assistant); and Ms Gillian Stephen (Former Research Assistant)

Clinical Effectiveness Committee: Dr Alison Black (Associate Specialist in Rheumatology, Grampian Osteoporosis Service, Woolmanhill Hospital, Aberdeen); Dr Audrey Brown (Consultant in Family Planning, The Sandyford Initiative, Glasgow/Chair of Clinical Effectiveness Committee); Dr Joan Burnett (General Practitioner, Links Medical Practice, City Hospital, Aberdeen); Dr Lucy Caird (Consultant in Gynaecology, Raigmore Hospital, Inverness); Dr Babatunde Gbolade,(Consultant Gynaecologist and Director of Fertility Control Unit, Department of Obstetrics, Gynaecology and Reproductive Medicine, St James's University Hospital, Leeds); Dr Louise Massey (Consultant in Public Health, Wolverhampton); Ms Shelley Mehigan (Nurse Specialist, Margaret Pyke Centre, Camden Primary Care Trust, London); Mrs Pat Murray (NHS Quality Improvement Scotland Representative/User Representative); Ms Nancy Robson (NHS Quality Improvement Scotland Representative/User Representative, Elgin). Written feedback was received from: Ms Toni Belfield (Former Director of Information, fpa, London); Professor Anna Glasier (Consultant in Sexual and Reproductive Health, Lothian Primary Care/Director of Sexual and Reproductive Health, University of Edinburgh, Edinburgh) and Dr Poornima Prabhu (Consultant in Family Planning, Contraception, Sexual and Reproductive Health, Britannia Court, Worcester). In addition, this Guidance document was independently peer reviewed by Professor Martha Hickey (Clinical Psychologist and Obstetrician Gynaecologist, School of Women's and Infants' Health, University of Western Australia) and Professor Daniel R Mishell Jr (Lyle G McNiele Professor, Department of Obstetrics and Gynecology, Keck School of Medicine, University of Southern California)

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

None

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Faculty of Sexual and Reproductive Healthcare Clinical Effectiveness Unit. Progestogen-only injectable contraception. London (UK): Faculty of Sexual and Reproductive Healthcare; 2008 Nov. 17 p. [101 references]

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Faculty of Sexual and Reproductive Health Care Web site.

Print copies: Available from the Faculty of Sexual and Reproductive Health Care, 27 Sussex Place, Regent's Park, London NW1 4RG

AVAILABILITY OF COMPANION DOCUMENTS

Discussion points and questions for progestogen-only implants developed by the Faculty of Sexual and Reproductive Healthcare are available at the end of the original guideline document.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on July 13, 2009. The information was verified by the guideline developer on August 18, 2009.

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